Appl. No. 10/772,913 Amdt. dated November 20, 2006 Reply to Office Action of September 21, 2006

### Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

# **Listing of Claims:**

#### 1-6. (canceled)

- 7. (Currently amended) The method of elaim 4 claim 52, wherein said cytokine is selected from the group consisting of hematopoietic growth factors, interleukins, interferons, immunoglobulin superfamily molecules, tumor necrosis factor family molecules and chemokines.
- 8. (Currently amended) The method of elaim-4 claim 52, wherein said cytokine is an interleukin.
- 9. (Currently amended) The method of elaim 4 claim 52, wherein said cytokine is selected from the group consisting of interleukin-2, interleukin-7, interleukin-12, interleukin-15, interleukin-18, and interferon- $\gamma$ .
- 10. (Currently amended) The method of claim 4 claim 52, wherein said cytokine is selected from the group consisting of interleukin-2, interleukin-12, interleukin-18, and interferon- $\gamma$ .
- 11. (Currently amended) The method of elaim 1 claim 52, wherein said transcription control sequences are selected from the group consisting of Rous sarcoma virus (RSV) control sequences, cytomegalovirus (CMV) control sequences, adenovirus control sequences and Simian virus (SV-40) control sequences.
- 12. (Currently amended) The method of elaim 1 claim 50, wherein said liposome delivery vehicle comprises lipids selected from the group consisting of multilamellar vesicle lipids and extruded lipids.

- 13. (Currently amended) The method of elaim 1 claim 50, wherein said liposome delivery vehicle comprises multilamellar vesicle lipids.
- 14. (Currently amended) The method of elaim 1 claim 50, wherein said liposome delivery vehicle comprises cationic liposomes.
- 15. (Currently amended) The method of elaim 1 claim 50, wherein said liposome delivery vehicle comprises pairs of lipids selected from the group consisting of DOTMA and cholesterol; DOTAP and cholesterol; DOTIM and cholesterol; and DDAB and cholesterol.
- 16. (Currently amended) The method of elaim-1 claim 50, wherein said liposome delivery vehicle comprises DOTAP and cholesterol.
- 17. (Currently amended) The method of claim 1 claim 50, wherein expression of said immunogen RNA in a tissue of said mammal elicits said immunogen-specific tumor antigen-specific immune response in said mammal.
- 18. (Currently amended) The method of elaim 1 claim 50, wherein administering said nucleic acid molecule RNA and said liposome elicit said systemic, non-specific immune response in said mammal.
- 19. (Currently amended) The method of claim 1 claim 50, wherein said mammal is selected from the from the group consisting of humans, dogs, cats, mice, rats, sheep, cattle, horses and pigs.
- 20. (Currently amended) The method of elaim 1 claim 50, wherein said mammal is a human.
  - 21-23. (canceled)
- 24. (Currently amended) The method of claim 22 claim 50, wherein said therapeutic composition comprises a plurality of recombinant nucleic acid molecules, each of said recombinant nucleic acid molecules comprising a cDNA sequence amplified from total

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RNA <u>is</u> isolated from an autologous tumor sample, each of said cDNA sequences encoding a tumor antigen or a fragment thereof and being operatively linked to a transcription control sequence.

- 25. (Currently amended) The method of elaim 22 claim 50, wherein said therapeutic composition comprises a plurality of recombinant nucleic acid molecules, each of said recombinant nucleic acid molecules comprising a cDNA sequence amplified from total RNA is isolated from a plurality of allogeneic tumor samples of the same histological tumor type, each of said cDNA sequences encoding a tumor antigen or a fragment thereof and being operatively linked to a transcription control sequence.
- 26. (Currently amended) The method of claim 22 claim 50, wherein said cancer is selected from the group consisting of melanomas, squamous cell carcinoma, breast cancers, head and neck carcinomas, thyroid carcinomas, soft tissue sarcomas, bone sarcomas, testicular cancers, prostatic cancers, ovarian cancers, bladder cancers, skin cancers, brain cancers, angiosarcomas, hemangiosarcomas, mast cell tumors, primary hepatic cancers, lung cancers, pancreatic cancers, gastrointestinal cancers, renal cell carcinomas, hematopoietic neoplasias, and metastatic cancers thereof.
- 27. (Currently amended) The method of elaim 22 claim 50, wherein said cancer is selected from the group consisting of a primary lung cancer and a pulmonary metastatic cancer.
- 28. (Currently amended) The method of elaim 22 claim 50, wherein said tumor antigen is from a cancer selected from the group consisting of melanomas, squamous cell carcinoma, breast cancers, head and neck carcinomas, thyroid carcinomas, soft tissue sarcomas, bone sarcomas, testicular cancers, prostatic cancers, ovarian cancers, bladder cancers, skin cancers, brain cancers, angiosarcomas, hemangiosarcomas, mast cell tumors, primary hepatic cancers, lung cancers, pancreatic cancers, gastrointestinal cancers, renal cell carcinomas, hematopoietic neoplasias and metastatic cancers thereof.

- 29. (Currently amended) The method of elaim 22 claim 50, wherein said tumor antigen is selected from the group consisting of tumor antigens having epitopes that are recognized by T cells, tumor antigens having epitopes that are recognized by B cells, tumor antigens that are exclusively expressed by tumor cells; and tumor antigens that are expressed by tumor cells and by non-tumor cells.
- 30. (Currently amended) The method of elaim-22 claim 50, wherein said expression of said tumor antigen administering produces a result selected from the group consisting of alleviation of said cancer, reduction of size of a tumor associated with said cancer, elimination of a tumor associated with said cancer, prevention of metastatic cancer, prevention of said cancer and stimulation of effector cell immunity against said cancer.
- 31. (Currently amended) The method of elaim 22 claim 50, wherein said expression of said tumor antigen in a pulmonary tissue by administration of said composition by an intravenous route prevents pulmonary metastatic cancer in said mammal.

## 32-49. (canceled)

- 50. (Original) A method to elicit a tumor antigen-specific immune response and a systemic, non-specific immune response in a mammal that has cancer, comprising administering to a mammal a therapeutic composition by a route of administration selected from the group consisting of intravenous and intraperitoneal administration, said therapeutic composition comprising:
  - (a) a, liposome delivery vehicle; and,
  - (b) total RNA isolated from a tumor sample, said RNA encoding tumor antigens.
- 51. (Original) The method of claim 50, wherein said route of administration is intravenous.

- 52. (Original) The method of claim 50, wherein said therapeutic composition further comprises a recombinant nucleic acid molecule having a nucleic acid sequence encoding a cytokine, said nucleic acid sequence being operatively linked to a transcription control sequence.
- 53. (Original) The method of claim 50, wherein said RNA is enriched for poly-A RNA prior to said administration to said mammal.

#### 54-55. (canceled)

- 56. (Currently amended) A composition for systemic administration to a <u>cancer</u> <u>afflicted</u> mammal <u>by intravenous or intraperitoneal administration</u> to elicit <del>an immunogen</del> <u>specific a tumor antigen-specific immune</u> response and a systemic, non-specific immune response, <u>said composition</u> comprising:
  - (a) a liposome delivery vehicle; and
  - (b) total RNA isolated from a tumor sample, said RNA encoding tumor

    antigens a recombinant nucleic acid molecule comprising an isolated nucleic acid
    sequence encoding an immunogen, said nucleic acid sequence being operatively
    linked to a transcription control sequence;

wherein said composition has a nucleic acid:lipid ratio of from about 1:1 to about 1:64.

- 57. (Currently amended) The method composition of claim 56, wherein said liposome delivery vehicle comprises lipids selected from the group consisting of multilamellar vesicle lipids and extruded lipids.
- 58. (Currently amended) The method composition of claim 56, wherein said composition has a nucleic acid:lipid ratio of from about 1:10 to about 1:40.
- 59. (Original) The composition of claim 56, wherein said liposome comprises multilamellar vesicle lipids.

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- 60. (Original) The composition of claim 56, wherein said liposome delivery vehicle comprises cationic liposomes.
- 61. (Original) The composition of claim 56, wherein said liposome delivery vehicle comprises pairs of lipids selected from the group consisting of DOTMA and cholesterol; DOTAP and cholesterol; DOTIM and cholesterol; and DDAB and cholesterol.
- 62. (Currently amended) The composition of claim 56, wherein said liposome delivery vehicle comprises <u>DOTAP DOTIM</u> and cholesterol.
- 63. (Original) The composition of claim 56, further comprising a pharmaceutically acceptable excipient.
- 64. (Original) The composition of claim 63, wherein said excipient comprises a non-ionic diluent.
- 65. (Original) The composition of claim 64, wherein said excipient is 5 percent dextrose in water (D5W).
- 66. (New) The method of claim 50, wherein said total RNA is isolated from an autologous tumor sample and in the form of a plurality of cDNA sequences amplified from said total RNA, each of said cDNA sequences being operatively linked to a transcription control sequence.
- 67. (New) The method of claim 50, wherein said total RNA is isolated from a plurality of allogeneic tumor samples of the same histological tumor type and in the form of a plurality of cDNA sequences amplified from said total RNA, each of said cDNA sequences being operatively linked to a transcription control sequence.